## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE MAR 2 6 2007 In get the Application of:

ASHDOWN

Application No.: 10/576,981

Examiner:

Filed: 4/24/2006

Art Unit: 1636

For: METHOD OF THERAPY

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §§ 1.97(b)(3) and 1.98)

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

The Examiner is requested to consider the references noted on the enclosed Form PTO/SB/08A (Substitute for form 1449A/PTO) during examination of the above-identified application. These references are submitted for the Examiner's consideration and are submitted pursuant to the duty of disclosure under 37 C.F.R. § 1.56. In submitting these references, no representation is made or implied that the references are or are not material to the examination of the application. The Examiner is encouraged to make his or her own determination of materiality.

Should any additional fees and/or any underpayment of fee(s); credit any overpayments be deemed necessary, such fees may be charged to Deposit Account No. 06-0029.

## Attorney Docket No. 335252

Should the examiner have any questions concerning the relevance of any reference cited in this disclosure, please contact the undersigned attorney.

Dated: March 19, 2007

Respectfully submitted,

Richard A. Nakashima Registration No. 42,023

Customer No. 35657

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135.4	PADENT		Application Number	10/576,981; CONFIRMATION 8112
INFO	DRMATION	DISCLOSURE	Filing Date	04/24/2006
STA	TEMENT BY	APPLICANT	First Named Inventor	Ashdown
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Sheet	1	of 20	Attorney Docket Number	335252

			U.S. PATENT	OCUMENTS	
Examiner	Cite	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevan
Initials *	No.1	Number - Kind Code <sup>2</sup> (if known)		Cited Document	Passages or Relevant Figures Appear
	1	US-5,939,400	8-17-1999	Steinman et al.	
	2	US- 2004/0203024	10-14-2004	Baker et al.	
	3	US- 6,110,898	8-29-2000	Malone et al.	
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F	Cite No.1 Foreign Patent Document  Country Code3 - Number4 - Kind Code5 (if known)	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant		
Examiner Initials*		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	Т <sup>6</sup>
	7	WO 02/13828 A1	2-21-2002	Ashdown		
	8	WO 03/068257	8-21-2003	Ashdown		
	9	WO 01/08702 A2	2-8-2001	Franchini		
	10	WO 03/070270 A1	8-28-2003	Ashdown		
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	12	WO 95/20660	8-3-1995	Robinson	<u>.</u>	
	13	EP 0 239 400 B1	9-30-1987	Winter	1	

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INFORMATION DIOCLOSURE	Application Number	10/576,981
INFORMATION DISCLOSURE	Filing Date	4/24/2006
STATEMENT BY APPLICANT	First Named Inventor	Ashdown ·
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Sheet 2 of 20	Attorney Docket Number	335252

	···	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

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		NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
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INFORMATION BIOOLOGUEE	Application Number	10/576,981 Confirmation 8112	
NFORMATION DISCLOSURE	Filing Date	4-24-2006	
STATEMENT BY APPLICANT	First Named Inventor	Ashdown	
	Art Unit		
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Sheet 4 of 20	Attorney Docket Number	335252	

		NON PATENT LITERATURE DOCUMENTS	-,
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	36	CASSINELLO, J. et al., "Phase II study of weekly irinotecan (CPT-11) as second-line treatment of patients with advanced colorectal cancer" Med Oncol. 2003; 20(1): 37-43	
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Examiner Signature	Date Considered	7

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INTERPRETATION DISCUSSIONE	Application Number	10/576,981 Confirmation 8112		
INFORMATION DISCLOSURE	riling Date	4-24-2006		
STATEMENT BY APPLICANT	First Named Inventor	Ashdown		
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Sheet 5 of $20$	Attorney Docket Number	335252		

		NON PATENT LITERATURE DOCUMENTS	,
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INFORMATION DISCLOSURE	Filing Date	4-24-2006
STATEMENT BY APPLICANT	First Named Inventor	Ashdown 2
	Art Unit	<u>P</u>
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Sheet 7 of 20	Attorney Docket Number	335252

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Substitute for form 14498/PTO		Complete if Known
INFORMATION DIGGLOCUES	Application Number	10/576,981; confirmation 8112
INFORMATION DISCLOSURE	Filing Date	4-24-2006
STATEMENT BY APPLICANT	First Named Inventor	Ashdown
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Sheet 14 of 20	Attorney Docket Number	335252

	,	NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials * No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ2
	146	POSNER, M., et al., "A phase II trial of continuous infusion cisplatin and 5-fluorouracil with oral calcium leucovorin in colorectal carcinoma" Am J. Clin Oncol. 1992 Jun; 15(3):239-41.	
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	168	MANETTA A., et al., "Cyclosporin enhancement of cisplatin chemotherapy in patients with refractory gynecologic cancer. A Gynecologic Oncology Group Study." Cancer. 1994 Jan. 1;73(1):196-9.	
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	179	LI, J.D., et al. "[Phase II clinical study of topotecan hydrochloride in patients with recurrent advanced ovarian cancer]" Ai Zheng. 2002 Apr;21(4):416-20.	
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	190	JEEN, YT, et al. "Phase II trial of epirubicin, cisplatin, oral uracil and tegafur, and leucovorin in patients with advanced gastric carcinoma." Cancer. 2001 Jun 15;91(12):2288-93.	
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	201	EINZIG, Al., et al., "Phase II trial of docetaxel (Taxotere) in patients with metastatic melanoma previously untreated with cytotoxic chemotherapy" Med oncol. 1996 Jun;13(2):111-7.	
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	212	CARR, B.I., et al., "Phase II study of Spherex (degradable starch microspheres) injected into the hepatic artery in conjunction with doxorubicin and cisplatin in the treatment of advanced-stage hepatocellular carcinoma: interim analysis." Semin Oncol. 197 Apr;24(2 Suppl 6):S6-97-S6-99.	
	213	CASCINU, S., et al. "A phase II study of Tomudex alternated with methotrexate, 5-fluorouracii, leucovorin in first-line chemotherapy of metastatic colorectal cancer." Ann Oncol. 199 Aug; 10(8):985-7.	
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	Application Number	10/576,981; Confirmation 8112
TRANSMITTAL	Filing Date	04/24/2006
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